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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,670	01/18/2005	Hideji Tajima	10287.65	2325

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EXAMINER	
POPA, ILEANA	
ART UNIT	**PAPER NUMBER**
1633	

MAIL DATE	DELIVERY MODE
09/14/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,670	TAJIMA, HIDEJI	
	Examiner	Art Unit	
	ILEANA POPA	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 September 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4,5,8-11,13,14 and 16-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 4, 5, 8-11, 13, 14, and 16-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/01/2010 has been entered.

Claims 2, 3, 6, 7, 12, and 15 have been cancelled. Claims 1 and 14 have been amended.

Claims 1, 4, 5, 8-11, 13, 14, and 16-20 are pending and under examination.

2. All rejections pertaining to claim 12 are moot because the applicant cancelled the claim in the reply filed on 09/01/2010.

The following rejections are withdrawn in response to the amendments to the claims filed on 09/01/2010:

The rejection of claims 1, 4, 5, 8, 9, 12-14, and 16-20 under 35 U.S.C. 103(a) as being unpatentable over Tajima (U.S. Patent No. 5,895,631);

The rejection of claims 1, 4, 5, 8-14, and 16-20 under 35 U.S.C. 103(a) as being unpatentable over Tajima (U.S. Patent No. 5,895,631), in view of both Tajima (U.S. Patent No. 5,919,706) and Tajima (U.S. Patent No. 6,100,079).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 4, 5, 8, 9, 13, 14, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tajima (U.S. Patent No. 5,895,631, of record), in view of each Moore (Current Protocols in Pharmacology, 1998, A.3C.1-A.C3.7), Gatlin et al. (Anal. Biochem., 1998, 263: 93-101, of record), and Kussmann-Gerber et al. (Analytical Biochemistry, 1999, 271: 102-105, of record).

Tajima teaches a pipette device for separating high molecular substances of interest (such as DNA), the device comprising a drawing/discharging section having a nozzle which connects to a detachable cylinder chip having an inlet/outlet, wherein the cylinder chip is loaded with magnetic particles coupled to biotin or streptavidin (i.e., a carrier housing), wherein the drawing/discharging section draws fluid into the cylinder chip via the inlet/outlet and discharges the fluid out of the cylinder chip via the same inlet/outlet; the magnetic particles are held in a predetermined position due to a magnetic field, and the cylinder chip comprises a small diameter section in contact with the fluid to be drawn, an intermediate diameter section which captures the magnetic particles, and a large diameter section (i.e., opening) detachably connected to the nozzle (claims 1, 2, 14, 19, and 20) (column 3, lines 50-67, column 4, lines 22-30 and 59-67, column 5, lines 14-22, column 6, lines 17-67, column 7, lines 7-27, 65, and 67,

column 8, lines 1-7, Fig. 7, claims 1, 3-5, and 9). Tajima teaches that the pipette device has a transferring section capable of transferring the carrier housing with respect to outside containers comprising different reagents (claims 1 and 16) (column 7, lines 37-48, column 8, lines 8-67). Tajima also teaches that the detachable chips can further contain filter tips capable of binding DNA, wherein the filter tips can contain silica filters i.e., porous glass (i.e., the pipette device contains a plurality of carrier kinds) (claims 5, 8 and 13) (column 4, lines 22-37, column 9, lines 33-40, column 13, lines 54-58, Fig. 7 and 13).

Tajima et al. teaches batch purification and not column purification by using non-magnetic particles having a diameter which is larger than the inlet/outlet (claims 1, 4, 9, and 14). However, using such is suggested by the prior art. For example, using non-magnetic particles to isolate DNA was routine in the prior art (see Moore, p. A.C3.4). Retaining non-magnetic particles within microcolumns by using an outlet having a diameter smaller than that of the particles was also routine in the prior art (see Gatlin et al., Abstract; p. 97, paragraph bridging columns 1 and 2). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the device of Tajima et al. by replacing their magnetic particles with non-magnetic particles and eliminating their magnetic body to achieve the predictable result of isolating DNA. Furthermore, one of skill in the art would have known that such a modification would require means of retaining the non-magnetic particles within the cylinder chip and would have found it obvious to achieve such by using particles with a diameter larger than the outlet, as taught by the prior art (i.e., column purification). One of skill in the art would

have been motivated to replace batch purification with column purification because the prior art teaches that column purification achieves a better separation than batch purification (see Kussmann-Gerber et al., Abstract; p. 104, column 2). One of skill in the art would have reasonably expected to be successful in doing such because the prior art teaches the successful use of non-magnetic particles to isolate DNA. It is noted that by doing such, one of skill in the art would necessarily remove the carrier through the large diameter section (claim 18).

With respect to the limitations of adhesion prevention section (claims 1, 9 and 14) such was common practice in the prior art; one of skill in the art would have known to use adhesion prevention and holding sections when needed.

Tajima et al., Moore, and Gatlin et al. do not teach their large diameter section as comprising a filter (claims 19 and 20). However, one of skill in the art would know to provide the large diameter section with a filter; one of skill in the art would be motivated to do so in order to avoid contaminating the pipette nozzle.

Thus, the claimed invention was *prima facie* obvious at the time it was made.

5. Claims 1, 4, 5, 8-11, 13, 14, and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tajima taken with each Moore, Gatlin et al., and Kussmann-Gerber et al., in further view of both Tajima (U.S. Patent No. 5,919,706, of record) and Tajima (U.S. Patent No. 6,100,07, of record).

The teachings of Tajima, Moore, Gatlin et al., and Kussmann-Gerber et al. are applied as above for claims 1, 4, 5, 8, 9, 13, 14, and 16-20. Although Tajima, Moore,

Gatlin et al., and Kussmann-Gerber et al. teach their device as useful for separating high molecular substances of interest, they do not specifically teach monitoring separation by using a translucent chip (i.e., a translucent carrier housing) and an outside apparatus for measuring luminescence on the carrier (claims 10 and 11). However, doing such is suggested by the prior art. For example, Tajima '079 teaches that pipette devices such as the ones disclosed by Tajima can be used to monitor the binding of high molecular substances of interest to magnetic beads, wherein monitoring takes place via luminescence (column 5, lines 40-54; column 7, lines 53-65). Although Tajima '079 does not specifically disclose translucent chips and an outside measuring apparatus, using such is taught by the prior art (see Tajima '706, column 3, lines 44-50; column 7, lines 34-45). It would have been obvious to one of skill in the art, at the time the invention was made, to modify the device of Tajima, Moore, Gatlin et al., and Kussmann-Gerber et al. according to the teachings of Tajima '079 and Tajima '706, to achieve the predictable result of monitoring the separation of the macromolecule of interest. With respect to the limitation of the carrier housing having a side face made in a plane (claim 11), one of skill in the art would know to modify the chip (i.e., the carrier housing) according to the measuring equipment used. Thus, the claimed invention was *prima facie* obvious at the time it was made.

The applicant's arguments are answered below to the extent that they pertain to the instant rejections.

The applicant argues that it would not have been obvious to modify Tajima '631 buy using non-magnetic particles because the magnetic properties of the particles are required by Tajima '631 in order to separate the magnetic particles from the reaction liquid and hold them within the chip. This is not found persuasive because one of skill in the art would have known that modifying Tajima '631 as proposed by the rejection above does not require magnetic properties to hold the particles within the chip.

The argument that the proposed modification would change the principle of operation of Tajima '631 is not new and was previously addressed. It is noted that the applicant asserts that batch purification is distinct from affinity chromatography. This is incorrect. Affinity chromatography could be performed either in batch or on column, i.e., affinity chromatography encompasses both batch and column purification. Furthermore, the prior art teaches that performing affinity chromatography on columns offers advantages over batch affinity chromatography (see the rejection above). Thus, one of skill in the art would have been motivated to modify Tajima '631 as indicated in the rejection above.

The arguments regarding Tajima '706 and Tajima '079 are not new and were previously addressed.

The applicant argues that the cited portion from the 6,530,288 patent does not disclose that the carrier is held in the housing section by its self-weight while fluid is drawn and discharged in two directions. In response, the claims only require the carrier to be held at the bottom of the carrier housing section by its self weight (please note that the non-magnetic particles disclosed in the rejection above would necessarily be held at

the bottom by their self weight). The claims do not recite that the carrier should be maintained at the bottom while fluid is drawn and discharged in two directions. Furthermore, the argument that the carrier in the 6,530,288 patent is not necessarily held without being adhered to the wall is just an argument not supported by any evidence. The specification clearly defines that projections are adhesion prevention sections (paragraph 0035) and thus, the projections taught by the 6,530,288 patent are adhesion prevention sections which prevent the carrier from adhering to the wall.

6. No claim is allowed. No claim is free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILEANA POPA whose telephone number is (571)272-5546. The examiner can normally be reached on 9:00 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ileana Popa/
Primary Examiner, Art Unit 1633